



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Institut de Cardiologie de Montréal
Serial No.: 2001-5324583
Filed: September 21, 2000
For: LOCAL DELIVERY OF 17-BETA ESTRADIOL FOR:
PREVENTING VASCULAR INTIMA HYPERPLASIA AND
FOR IMPROVING VASCULAR ENDOTHELIAL FUNCTION
AFTER VASCULAR INJURY
Examiner: Hidenori ARAKI

DECLARATION

Dear Sir:

1. I, Richard Sean Stack, M.D., FACC, residing at 106 Alder Place, Chapel Hill, NC 27517, am Professor Emeritus of Cardiology at Duke University Medical Center, Erwin Rd., Durham, NC. 27710
2. I have been conducting research in the field of angioplasty and restenosis for 26 years and have published more than 350 scientific publications on the subject. I have numerous close associates in the Japanese Cardiology Community and have appeared as Guest of Honor at many Japanese national meetings such as the Japanese Coronary Association. Please find enclosed a copy of my resume.

Blood vessels, endothelium and smooth muscle cells

3. All blood vessels follow a similar histological makeup in the arterial system. The inner lining is the endothelium, followed by subendothelial connective tissue. Then follows a muscular layer of vascular smooth muscle. Finally, there is a further layer of connective tissue termed the adventitia, which contains nerves that supply the muscular layer, as well

as nutrient capillaries in the larger blood vessel. The amount of collagen and elastic fibers within the vessel wall can vary with the size of a given vessel.

4. The endothelium is a layer of thin, flat cells, i.e. endothelial cells, that lines the interior surface of blood vessels, forming an interface between circulating blood in the lumen and the rest of the vessel wall.
5. Endothelial cells are distinct by their function and by their nature from smooth muscle cells. Smooth muscle cells are responsible for the contraction and dilatation of blood vessels. Endothelial are characterized by their permeability and thus assist in absorbing nutrients from the blood and releasing them in surrounding tissues. Endothelial cells also play a role in inflammation and are responsible for the release of a vasodilator, namely nitric oxide and other anti-thrombotic substances like tissue-plasminogen activator.

Restenosis

6. When an abnormal narrowing of a blood vessel's channel (i.e. stenosis), occurs, it may be necessary to insert a device in the vessel to increase the channel's size. This revascularization technique is called angioplasty. During angioplasty, the blood vessel may be injured by the insertion of the device. The injury to the vessel generally consists in scraping away the first layers of the blood vessel wall including the innermost layer, the endothelium and variable tearing of the atherosclerotic wall.
7. This injury may then lead to a "restenosis", namely a re-obstruction of the blood vessel channel. This re-obstruction is the result of a number of events including pathological proliferation and migration of smooth muscle cells which cause thickening of the blood vessel wall and a narrowing of the blood vessel wall.

Prevention of restenosis

8. In order to prevent restenosis, it is thus useful to inhibit smooth muscle cell proliferation, namely prevent smooth muscle cells to multiply.
9. More recently, it was found however that in order to prevent restenosis, it is also useful to promote vessel repair, namely promote the regeneration of the endothelium and consequently a restoration of the endothelial function such as nitric oxide release. The regeneration of endothelium is also called "reendothelialization".
10. There are a number of agents known to prevent or reduce smooth muscle cell proliferation and/or to prevent or reduce blood vessel wall thickening. In fact most anti-restenosis agent are anti-proliferative agents that seek to prevent proliferation of smooth muscle cells.
11. Very few agents are known to promote blood vessel wall repair. In fact, until recently, very few appreciated the usefulness of regenerating the endothelium. On the contrary, many believed in a toxic approach such as brachytherapy to kill smooth muscle cells and avoid the endothelium to repair.
12. It is my experience that it cannot be predicted whether an agent known to prevent or reduce smooth muscle cell proliferation and/or to prevent or reduce blood vessel wall thickening will also promote reendothelialization.
13. Indeed, substances able to inhibit smooth muscle cell proliferation or migration do not systematically also improve reendothelialization or vascular function. Hence paclitaxel and sirolimus are anti-proliferative agents that do not promote reendothelialization.
14. In my opinion therefore, the knowledge that beta-estradiol had an ability to reduce smooth muscle cell proliferation was not sufficient, for someone

skilled in the art, to predict that beta-estradiol could also promote reendothelization and endothelial function.

15. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true.

Respectfully submitted,

7-25-05

Date

Richard S. Starke

CURRICULUM VITAE

RICHARD SEAN STACK, M.D., F.A.C.C.

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DATE OF BIRTH: May 14, 1949 (Detroit, Michigan)

MEDICAL EDUCATION:

1972-1976	Wayne State University Medical School, Detroit, Michigan
1976-1977	Internship (Internal Medicine), Harper Hospital, Wayne State University, Detroit, Michigan
1977-1978	Residency (Internal Medicine), Harper Hospital, Wayne State University, Detroit, Michigan
1978-1979	Chief Resident (Internal Medicine), Harper Hospital, Wayne State University, Detroit, Michigan
1979-1982	Fellowship (Cardiology), Duke University Medical Center, Durham, North Carolina 27710

MEDICAL POSITIONS AND POSTS:

1982-1983	Instructor in Medicine (Cardiology), Duke University Medical Center, Durham, North Carolina 27710
1982-1984	Senior Staff Physician, Director, Coronary Care Unit, Durham VA Medical Center, Durham, North Carolina 27710
1983-1989	Assistant Professor of Medicine (Cardiology), Duke University Medical Center, Durham, North Carolina 27710
1983-2002	Founder and Director of Interventional Cardiology, Duke University Medical Center, Durham, North Carolina 27710
1989-1997	Associate Professor of Medicine (Cardiology, tenured), Duke University Medical Center, Durham, North Carolina 27710
1997-2002	Professor of Medicine (Cardiology, tenured), Duke University Medical Center, Durham, North Carolina 27710
2002-Present	Professor Emeritus, Dept. of Medicine (Cardiology)

GRANTS AND AWARDS:

1. Wayne State University Research award for best medical student research - 1976.
2. Duke University Inman award for best basic science research in cardiology - 1980.
3. GRANT: Coronary Blood Flow Velocity in Ischemic Heart Disease NHLB1 No. R01 HL37608-01 - Active 1987-1990, Principal Investigator
4. GRANT: Bypass Angioplasty Revascularization Investigation (BARI) Clinical Trial NHLB1 NO. UO1 HL38516-01 - Active 1987-1991, Co-principal Investigator
5. GRANT: Development of Peripheral and Coronary Vascular Bioabsorbable Stent Prostheses NHLB1 No. 2 P50 HL17670-16 - Active 1990-1991, Principal Investigator
6. International Award for Best Experimental Research in 1995 presented by Erasmus University Thoraxcenter, Netherlands.
7. Who's Who In America - Cardiology - 1997
8. The Best Doctors in America - Cardiology - 1997
9. Distinguished Alumni Award, Wayne State University School of Medicine 2001
10. Professor Emeritus granted by Duke Board of Trustees
11. "Richard S. Stack, MD Professorship" Permanent Endowed Chair -- Duke University

ORGANIZATIONS:

American Heart Association
 American College of Cardiology
 American Medical Association
 North Carolina Medical Society
 North Carolina Heart Association
 Duke Biomedical Engineering Industrial Advisory Board

CERTIFICATIONS:

Board Certification: American Board of Internal Medicine
 Subspecialty Board Certification: American Board of Internal Medicine, Cardiology
 Fellow, American College of Cardiology

MEDICAL LICENSURE:

North Carolina
 California

INTERVENTIONAL DEVICE INVENTIONS: (55 US Patents and Patents Pending)

A. Patents Issued: (24 patents)

January 13, 2004	6,675,809	Satiation devices and methods
January 6, 2004	6,673,891	Polymers for delivering nitric oxide in vivo
November 11, 2003	6,645,223	Deployment and recovery control systems for embolic protection devices
July 15, 2003	6,592,616	System and device for minimizing embolic risk during an interventional procedure
April 1, 2003	6,540,722	Embolic protection devices
January 14, 2003	6,506,203	Low profile sheathless embolic protection system
November 19, 2002	6,481,262	Stent crimping tool
October 22, 2002	6,468,299	Stent delivery catheter with bumpers for improved retention of balloon expandable stents
August 20, 2002	6,436,132	Composite intraluminal prostheses
June 11, 2002	6,403,759	Polymers for delivering nitric oxide in vivo
November 27, 2001	6,322,490	Radioactive stent structures
July 24, 2001	6,264,683	Stent delivery catheter with bumpers for improved retention of balloon expandable stents
July 24, 2001	6,264,671	Stent delivery catheter and method of use

CURRICULUM VITAE

RICHARD SEAN STACK, M.D.

May 15, 2001	6,232,434	Polymers for delivering nitric oxide in vivo
December 26, 2000	6,165,196	Perfusion-occlusion apparatus
October 31, 2000	6,139,511	Guidewire with variable coil configuration
June 23, 1998	5,770,645	Polymers for delivering nitric oxide in vivo
June 18, 1996	5,527,337	Bioabsorbable stent and method of making the same
August 30, 1994	5,342,393	Method and device for vascular repair
April 26, 1994	5,306,286	Absorbable stent
October 22, 1991	5,059,211	Absorbable vascular stent
March 6, 1990	4,905,689	Method of using a laser catheter
September 19, 1989	4,867,156	Percutaneous axial atheroectomy catheter assembly and method of using the same
August 8, 1989	4,854,315	Laser catheter

B. Patents Pending and Published by US Patent Office: 19 Patent Applications

Filed Date	Application Number	
September 15, 2003	20040088002	Deployment and recovery control systems for embolic protection devices
June 9, 2003	20030199991	Satiation devices and methods
June 9, 2003	20030199990	Satiation devices and methods
June 9, 2003	20030199989	Satiation devices and methods
May 29, 2003	20030195556	System and device for minimizing embolic risk during an interventional procedure
March 10, 2003	20030212361	Embolic protection devices
January 16, 2003	20040117031	Satiation devices and methods
June 5, 2002	20030078365	Novel polymers for delivering nitric oxide in vivo
April 8, 2002	20030040808	Satiation devices and methods
August 27, 2001	20030040804	Satiation devices and methods
August 13, 2001	20030032941	Convertible delivery systems for medical devices
July 31, 2001	20010051822	Self-expanding stent with enhanced delivery precision and stent delivery system
June 20, 2001	20020124626	Stent crimping tool
June 19, 2001	20010037126	Stent delivery catheter and method of use

CURRICULUM VITAE

RICHARD SEAN STACK, M.D.

June 7, 2001	20010044630	Stent delivery catheter with bumpers for improved retention of balloon expandable stents
June 7, 2001	20010044630	Stent delivery catheter with bumpers for improved retention of balloon expandable stents
April 30, 2001	20020161389	Deployment and recovery control systems for embolic protection devices
December 29, 2000	20010020083	Novel Polymers for Delivering nitric oxide in vivo
December 22, 2000	20020042625	Perfusion-occlusion apparatus and methods

C. Patents Pending - Submitted to Patent Office and not yet published (less than 18 months since submission): 12 Patent Applications

BOARD OF DIRECTORS

Barosense Inc

Bioabsorbable Vascular Solutions Inc

IRM Inc.

Interventional Therapeutic Solutions Inc

CellPace Inc.

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EXTRACURRICULAR ACTIVITIES:

- Martial arts: 6TH Degree Black Belt: To Shin Do
9th Degree Black Belt: Ninjustsu

SCIENTIFIC PUBLICATIONS: 333 Manuscripts, Chapters, Books, and Abstracts

ABSTRACTS

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3. Sohn YH, Stack RS, Taylor M, Weissler AM. The sensitivity and specificity of systolic time intervals in detecting abnormal left ventricular performance in coronary artery disease. *Circulation* 56:II, 1977.
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